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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/777,920 | 02/07/2001 | Jacques Dumas | BAYER 15 P3 | 6183 |

23599 7590 03/14/2007

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| EXAMINER | |
|---|---|
| DESAI, RITA J | |
| ART UNIT | PAPER NUMBER |
| 1625 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 03/14/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/777,920 | DUMAS ET AL. | |
| | Examiner | Art Unit | |
| | Rita J. Desai | 1625 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,9,10,12,14-18,20-30,34-37,39,40,42 and 45-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 9, 10, 12, 14-18, 20-30, 34-37, 39, 40, 42, 45-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/2006 has been entered and the examination on the same follows.

The claims pending are 1-5, 9, 10, 12, 14-18, 20-30, 34-37, 39, 40, 42, 45-49 are pending.

The rejection of the claims 1-5, 9, 10, 12 , 14-18, 20-30, 35-37, 39, 40, 42, 45-49 under 35 USC 112 first paragraph still stands.

It is being repeated here.

The applicants do not have any written description of which groups are included when they claim a carbon moiety of up to 24 carbon atoms optionally containing hetero atoms .....

The examiner has in fact.

**The breadth of the claims:** The instant claims encompass many compounds from an aromatic carbocyclic moiety to an aromatic carbocyclic moiety having many large electron withdrawing and bulky groups substituted on it to a moiety having many heterocyclic rings. These compounds cover a very wide range of compounds.

**The state of the prior art:** The state of the prior art is that the drugs and the enzymes react in a lock and key mechanism and the structure of the compound has to be specific. Even a difference of a methyl group verses a hydrogen changes the properties altogether. A good example is a theophylline verses caffeine . They differ by just a methyl group but one of them has a pharmaceutical use as a bronchodilator. There is no absolute predictability and no established correlation between the different substitutions on a core that they would all behave in the exact same way. The existence of these obstacles establishes that the contemporary knowledge in the

art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face..
Applicants claims are drawn to a method of treating solid tumors. And treating tumors is still uncertain and unpredictable.
**The level of predictability in the art:** It is noted that the pharmaceutical art is unpredictable , requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. The level of unpredictability is in the art is very high. The compounds which differ by a methyl group also show different properties, for e.g. theophylline and caffeine. One of them is a bronchodilator and they differ only by a methyl group.

Thus with highly unpredictability of the art applicants should provide more evidence that their compounds with the various 1-24 carbons and so on have the same effect.
The generic nebulous description of the groups surrounding the core does not enable nor exactly describe what the specific compound is! Pharmaceutical art, is not only unpredictable but has to be very specific as the presence or absence of a substitutions and groups can have an effect on not only the effectiveness, but the bioavailability and enablement of the compounds structurally and also in the treating of tumors.

The "pharmaceutical" compositions claims, with the term "pharmaceutical" implies that the compositions have the capability of effective treating a diseases or a disorder which is not enabled in the specification, hence the term "pharmaceutical" compositions is also not enabled.

Thus the rejections under 35 USC 112 written description and scope of enablement still stands.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to compounds with a generic description of groups having ""1-30 carbon atoms" or

"C1-C12 cycl.oalkyl with 0 to 3 hetero atoms" or

"C3-C 12 heteroaryl groups having 1-3 heteroatoms" or

"C7 to C24 alkaryl," or " 5-7 membered hetero cyclic structure of 1-3 heteroatoms selected from N, S and O " or "5-6 membered monocyclic hetero aryl having 1-4 hetero atoms

selected from a group consisting of O,N, and S or 8-10 membered bicyclic hetero aryl having 1-6 hetero atoms selected from a group consisting of O, N and S optionally substituted with 1-3 substitutions " . Such generic language without any definition of which groups are encompassed by them gives no guidance as to what the group is and how and where it is attached. The specification has some examples however there is no definition of the terms. There is no structure given to this group. Note all the groups recited are generic groups. The generic groups includes a plethora of compounds.

The expression """"1-30 carbon atoms" or

"C1-C12 cycl.oalkyl with 0 to 3 hetero atoms" or

"C3-C 12 heteroaryl groups having 1-3 heteroatoms" or

"C7 to C24 alkaryl," or " 5-7 membered hetero cyclic structure of 1-3 heteroatoms selected from N, S and O " or "5-6 membered monocyclic hetero aryl having 1-4 hetero atoms selected from a group consisting of O,N, and S or 8-10 membered bicyclic hetero aryl having 1-6 hetero atoms selected from a group consisting of O, N and S optionally substituted with 1-3 substitutions "" without i.e. partial or complete structure does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. Claims employing generic language at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of compounds and applicants claimed expression represents only an invitation to experiment regarding possible compounds.

Applicants argue that there are examples that include hetero groups and aryls and such which may fall within the scope of the definition, however the examples do not cover the full scope of the claims.

In re Kirk, 153 USPQ 48. If you the "public" find that it works, I claim it, is not a proper basis of patentability.

The Double patenting rejection of the claim over 10/788029 and 10/361,858 and 10/848567 all still stands.

Applicants arguments that in their compounds the L' is substituted by SO2Rx, C(0)Rx and –C(NRy)Rz is not convincing. Even though the exact species is not disclosed the applications still disclose the equivalency of these substitutions. See ZB and ZC, the substitution on the L' would be obvious to be C(0)Rx , wherein Rx id NraRb.

The CN group is the precursor of the CORx groups .

Thus the rejections still stands.

***Conclusion***

Claims 1-5, 9, 10, 12, 14-18, 20-30, 34-37, 39, 40, 42, 45-49 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
March 9, 2007